From: Charles Boyd <CharlesB@Safechain.com>
Sent: Wed 11/25/2020 5:13:16 PM (UTC)
To: Abbie Divilio <AbbieD@Safechain.com>
Subject: FW: Compliance call

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From: John E. Morrone <JMorrone@FrierLevitt.com>
Sent: Wednesday, October 14, 2020 11:34 AM
To: Charles Boyd <CharlesB@Safechain.com>
Subject: FW: Compliance call

From: Martha M. Rumore <mrumore@frierlevitt.com>
Sent: Tuesday, October 13, 2020 8:05 PM
To: John E. Morrone <JMorrone@FrierLevitt.com>
Subject: RE: Compliance call

Hi John:

See brief answers below.

1) T3 (**Transaction** Hx- starts with manufacturer, **Tx** info- stuff on the invoice, **Tx** statement- just a statement that is made by the trading partner) info MUST be exchanged at the time of change of ownership of the product. At the same time, wholesale distributors, repackagers, and dispensers cannot accept ownership of a product unless they are provided with associated T3 data. The T3 data requirements mandate all parties who have ownership of a product need to keep that product's T3 data for 6 years.

2) FDA Form 3911 is to notify FDA about illegitimate product which they define as "are or may be counterfeit, diverted, stolen, intentionally adulterated, unfit for distribution or the subject of a fraudulent transaction." Interestingly, the FDA Guidance never mentions T3 as the basis for this determination. FDA gets very few of these 3911 forms (~<200/yr) and they are mostly filled out by manufacturers. In 2018, the vast majority (120) came from drug manufacturers (mostly product returns); 22 from wholesale distributors, and only 8 from dispensers.

The scenario is unclear to me without knowing more; did Giliad sell drug to SafeChain. If so,

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they needed to provide T3 data? They need to fill out the form.

3) If a product is thought suspect, or is found to be counterfeit, the product needs to be quarantined and investigated. We cannot answer without knowing details such as what P&P's were used to clear the product. Have they heard from the manufacturer regarding their investigation?

Let me know if you want me on the call tomorrow.

Best,

Martha M. Rumore, PharmD, MS, JD, LLM
Senior Counsel

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From: John E. Morrone <JMorrone@FrierLevitt.com>
Sent: Tuesday, October 13, 2020 5:44 PM
To: Martha M. Rumore <mrumore@frierlevitt.com>
Subject: FW: Compliance call

Can you help answer these questions?

Very truly yours,

John E. Morrone, Esq.

Partner

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From: Charles Boyd <CharlesB@Safechain.com>
Sent: Tuesday, October 13, 2020 5:43 PM
To: John E. Morrone <JMorrone@FrierLevitt.com>
Subject: Compliance call

Hey John,

Do you have any availability tomorrow to discuss a few compliance topics listed below?

1. T3 requirements – we have tried to verify each transaction on the T3 and have not had any luck with AmerisourceBergen. They refused to provide us with any information. So I guess my question is, if we cannot verify the transaction is it still ok to accept and sell the goods based off the T3 info our supplier provides?
2. FDA Form 3911. Gilead told our compliance team that if we cannot verify a T3 transaction that we need to fill one of these out. This was after they requested our invoice from our supplier and we refused. Is this a requirement or just a recommendation? It seems a little over the top and we're not familiar with FDA requirements since we're not licenses by the FDA.
3. We stopped selling that one lot# we had an issue with several weeks ago. Do you think we can now continue to sell since the issue was with just 1 bottle out of about 30 we sold?

Hope all has been well. Thanks!

CB

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